



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2014-0600; FRL-9933-25]

#### Teflubenzuron; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of teflubenzuron [*N*-[[[(3,5-dichloro-2,4-difluorophenyl)amino]carbonyl]-2,6-difluorobenzamide] in or on multiple commodities which are identified and discussed later in this document. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0600, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency

Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDfRNotices@epa.gov](mailto:RDfRNotices@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).

- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at

[http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0600 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0600, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of January 28, 2015 (80 FR 4525) (FRL-9921-55), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E8230) by BASF Corporation, 26 Davis Dr., Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide teflubenzuron, in or on apple at 0.5 parts per million (ppm); apple, wet pomace at 0.8 ppm; broccoli at 0.2 ppm; cattle, meat byproducts at 0.01 ppm; cattle, muscle at 0.01 ppm; cauliflower at 0.01 ppm; citrus, oil at 90 ppm; coffee, bean, green at 0.6 ppm; corn, field, grain at 0.01 ppm; corn, field, refined oil at 0.02 ppm; egg at 0.01 ppm; goat, meat byproducts at 0.01 ppm; goat, muscle at 0.01 ppm; horse, meat byproducts at 0.01 ppm; horse, muscle at 0.01 ppm; lemon at 0.9 ppm; mango at 1.5 ppm; melon, at 0.3 ppm; milk at 0.01 ppm; orange at 0.6 ppm; papaya at 0.4 ppm; pineapple at 0.8 ppm; pork, muscle at 0.01 ppm; pork, meat byproducts at 0.01 ppm; poultry, meat byproducts at 0.01 ppm; poultry,

muscle at 0.01 ppm; sheep, meat byproducts at 0.01 ppm; sheep, muscle at 0.01 ppm; soybean, hulls at 0.4 ppm; soybean, seed at 0.05 ppm; sugarcane, cane at 0.01 ppm; sunflower, seed at 0.3 ppm; tomato at 1.5 ppm; and tomato, paste at 5 ppm. That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. No tolerance-related comments were submitted. Based upon review of the data supporting the petition, EPA has edited tolerance levels for some food commodities, and declined to grant tolerances for others. The reasons for these changes are explained in Unit IV.C.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for teflubenzuron including exposure resulting from the

tolerances established by this action. EPA's assessment of exposures and risks associated with teflubenzuron follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Exposure of animals to teflubenzuron has shown no evidence of neurotoxicity, immunotoxicity, or genotoxicity. It is categorized as having low acute lethality by oral, dermal and inhalation routes of exposure. It is not a dermal sensitizer or eye irritant. In all species tested, hepatotoxicity was indicated. The liver is the primary target organ for teflubenzuron. In the mouse, which is the most sensitive species compared to the rat and the dog, liver adenomas were observed following chronic exposure. Increased enzyme release and numerous microscopic indicators of liver injury (diffuse hypertrophy, disseminated single-cell necrosis, patchy glycogen storage, Kupffer cell proliferation, phagocytic foci, lipofuscin accumulation and centrilobular fatty change) were observed in all species exposed to teflubenzuron.

The 2-generation reproductive study shows evidence of increased quantitative offspring susceptibility. There were no effects of teflubenzuron exposure on the parental generation, but effects on offspring consisted of decreased F<sub>2</sub> litter weights and increased incidence of unilateral dilatation of the renal pelvis in F<sub>1</sub> offspring. There is no evidence of increased fetal susceptibility in either the rat or rabbit developmental studies.

Because rare liver tumors were observed only in male mice and there was no evidence of carcinogenicity from teflubenzuron in female mice or in male or female rats, the Agency is

using a non-linear approach (i.e. reference dose (RfD)) to account for the observed carcinogenicity that could result from exposure to teflubenzuron. Moreover, there is no concern for mutagenicity.

Specific information on the studies received and the nature of the adverse effects caused by teflubenzuron as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document, “Teflubenzuron: Human Health Risk Assessment” at pp. 4, 13, 21, and 22 in docket ID number EPA-HQ-OPP-2014-0600.

#### *B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a RfD - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for teflubenzuron used for human risk assessment is shown in Table 1 of this unit.

**Table 1.--Summary of Toxicological Doses and Endpoints for Teflubenzuron for Use in Human Health Risk Assessment**

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary  (General population including infants and children)	An endpoint of concern attributable to a single dose was not identified.  An acute RfD was not established		
Chronic dietary  (All populations)	NOAEL = 2.1 mg/kg/day $UF_A = 10x$  $UF_H = 10x$  FQPA SF = 1x	Chronic RfD  = 0.021 mg/kg/day   cPAD = 0.021 mg/kg/day	Carcinogenicity (mouse) LOAEL = 10.5 mg/kg/day based on increased microscopic lesions in the liver (diffuse hypertrophy, centrilobular single-cell necrosis, patchy glycogen storage, Kupffer cell proliferation, phagocytic foci, and centrilobular fatty



			change) associated with increased relative liver weight
Cancer (Oral, dermal, inhalation)	The Agency is using a non-linear approach (i.e., RfD) that will adequately account for all chronic toxicity, including carcinogenicity that could result from exposure to teflubenzuron		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. mg/kg/day = milligram/kilogram/day. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies).

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to teflubenzuron, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from teflubenzuron in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for teflubenzuron; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed teflubenzuron residues are present in all commodities at tolerance levels and that 100% of all crops are treated.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a non-linear RfD approach is appropriate for assessing cancer risk to teflubenzuron. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii. *chronic exposure.*

iv. *Anticipated residue and percent crop treated (PCT) information.*

EPA did not use anticipated residue and/or PCT information in the dietary assessment for teflubenzuron. Tolerance-level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* Because there are no domestic agricultural or residential uses registered or proposed for teflubenzuron, there will be no exposure in drinking water; therefore, a drinking water assessment is not necessary.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Teflubenzuron is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative

effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found teflubenzuron to share a common mechanism of toxicity with any other substances, and teflubenzuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that teflubenzuron does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The rat 2-generation reproductive study showed evidence of increased quantitative offspring susceptibility to teflubenzuron. While there were no parental effects, adverse offspring effects were observed and consisted of decreased F<sub>2</sub> litter weights and increased incidence of unilateral dilatation of the renal pelvis in F<sub>1</sub> offspring. There were no effects of teflubenzuron in the developmental rat study up to the highest dose tested.

In the developmental rabbit study, maternal effects were observed at the limit dose and were consistent with liver toxicity; no fetal effects were observed.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for teflubenzuron is complete for assessing the safety of tolerances for which there is no associated U.S. pesticide registration.
- ii. There is no indication that teflubenzuron is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.
- iii. As discussed in Unit III.D.2., there is evidence of quantitative susceptibility in the rat in the 2-generation reproductive study. There is no residual concern or uncertainty regarding these effects as the study established a clear NOAEL and LOAEL. Moreover, the Agency is using a lower POD in its assessment, which will be protective of these effects.
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. There are no drinking water or residential exposures as there are no U.S. registrations of pesticides containing teflubenzuron. These assessments will not underestimate the exposure and risks posed by teflubenzuron.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For

linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, teflubenzuron is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to teflubenzuron from food and water will utilize 50% of the cPAD for children 1-2 years old the population group receiving the greatest exposure. There are no residential uses for teflubenzuron.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Teflubenzuron is for use on imported commodities only, no residential exposure or chronic exposure from water is expected. Because no short-term adverse effect was identified, teflubenzuron is not expected to pose a short-term risk.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate-term adverse effect was identified, teflubenzuron is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* Based on the results of the chronic assessment, EPA concludes that teflubenzuron will not pose a cancer risk for the U.S. population.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to teflubenzuron residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

The petitioner submitted a high-performance liquid chromatography method with tandem mass-spectrometry detection (LC/MS/MS) analytical method, BASF Method L0160/01, for analysis of residues of teflubenzuron in/on dry and oily crop commodities. The method has been adequately validated by the petitioner as well as by an independent laboratory, and was also adequately radio validated using weathered samples obtained from metabolism studies. In addition, the Quechers multi residue method (MRM) is considered suitable for the analysis of teflubenzuron in fruits and vegetables.

Adequate enforcement methodology (high-performance liquid chromatography with tandem mass spectrometry) is available to enforce the tolerance expression.

##### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section

408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established a MRL for teflubenzuron in or on pome fruit at 1.0 ppm. The U.S. tolerance being established for residues of teflubenzuron on apples is harmonized with this value.

#### *C. Revisions to Petitioned-For Tolerances*

The petition requested tolerances for several livestock commodities (cattle, meat byproducts; cattle, muscle; egg; goat, meat byproducts; goat, muscle; horse, meat byproducts; horse, muscle; milk; pork, meat byproducts; pork, muscle; poultry, meat byproducts; poultry, muscle; sheep, meat byproducts; and sheep, muscle.) Based on the results of livestock feeding studies, EPA is not establishing tolerances for these commodities because there is no expectation of finite residues in livestock commodities. The tolerance proposal for apple, wet pomace is not being established because the commodity is not likely to be imported. The petitioned-for tolerance for tomato, paste is not being established because concentration of residues is not expected above the tolerance established for tomato (1.5 ppm); the tolerance for tomato will be adequate to cover any residues in tomato paste.

In the case of apple, EPA is establishing a higher tolerance (from 0.5 ppm to 1.0 ppm) to harmonize with the established Codex MRL. Based on EPA's methods for calculating residue levels on processed commodities, EPA is establishing a higher tolerance for citrus, oil (90 ppm to

100 ppm) and a lower tolerance for soybean, hulls (0.4 ppm to 0.15 ppm) than what was requested. Using the Organization for Economic Cooperation and Development (OECD) calculation procedures, EPA is establishing a higher tolerance for papaya tolerance (0.4 ppm to 0.5 ppm) and a lower tolerance for the lemon (0.90 ppm to 0.80 ppm) than was requested.

In addition, EPA is adding significant figures to tolerance levels in accordance with EPA policy for the following commodities: Broccoli; coffee, bean, green; melon, subgroup 9A; orange; pineapple; and sunflower, seed. EPA is also revising the commodity term “corn, field” to “corn, field, grain” to be consistent with the food and feed commodity vocabulary used for tolerances. Finally, EPA is establishing a tolerance for “melon, subgroup 9A” instead of “melon” as requested because the regulatory definition of “melon” includes all commodities listed under “melon, subgroup 9A.”

## **V. Conclusion**

Therefore, tolerances are established for residues of teflubenzuron, in or on apple at 1.0 ppm; broccoli at 0.20 ppm; cauliflower at 0.01 ppm; citrus, oil at 100 ppm; coffee, bean, green at 0.60 ppm; corn, field, grain at 0.01 ppm; corn, field, refined oil at 0.02 ppm; lemon at 0.80 ppm; mango at 1.5 ppm; melon, subgroup 9A at 0.30 ppm; orange at 0.60 ppm; papaya at 0.50 ppm; pineapple at 0.80 ppm; soybean, seed at 0.05 ppm; soybean, hulls at 0.15 ppm; sugarcane, cane at 0.01 ppm; sunflower, seed at 0.30 ppm; and tomato at 1.5 ppm.

## **VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and



Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In

addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 20, 2015.

Jack E. Housenger,

*Director, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Add § 180.687 to subpart C to read as follows:

**§ 180.687 Teflubenzuron; tolerances for residues.**

(a) *General.* (1) Tolerances are established for residues of the insecticide teflubenzuron, including its metabolites and degradates, in or on the commodities in the table below.

Compliance with the tolerance levels specified below is to be determined by measuring only teflubenzuron (*N*-[[[(3,5-dichloro-2,4-difluorophenyl)amino]carbonyl]-2,6-difluorobenzamide).

Commodity	Parts per million
Apple <sup>1</sup>	1.0
Broccoli <sup>1</sup>	0.20
Cauliflower <sup>1</sup>	0.01
Citrus, oil <sup>1</sup>	100
Coffee, bean, green <sup>1</sup>	0.60
Corn, field, grain <sup>1</sup>	0.01
Corn, field, refined oil <sup>1</sup>	0.02
Lemon <sup>1</sup>	0.80
Mango <sup>1</sup>	1.5
Melon, subgroup 9A <sup>1</sup>	0.30
Orange <sup>1</sup>	0.60
Papaya <sup>1</sup>	0.50

Pineapple <sup>1</sup>	0.80
Soybean, seed <sup>1</sup>	0.05
Soybean, hulls <sup>1</sup>	0.15
Sugarcane, cane <sup>1</sup>	0.01
Sunflower, seed <sup>1</sup>	0.30
Tomato <sup>1</sup>	1.5

<sup>1</sup> There are no U.S. registrations as of [*insert date of publication in the **Federal Register***]

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 2015-27593 Filed: 10/29/2015 8:45 am; Publication Date: 10/30/2015]